University of Alberta

The Acute Effect of Acupuncture on 20km Cycling Performance

by

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Abstract

Introduction: The acute effects of acupuncture on 20 km cycling performance were examined. **Methods**: Twenty subjects (26.3±3.9 years) underwent three stationary cycling tests a week apart. Before each, they received: acupuncture (test A), "sham" acupuncture (test B), or nothing (control, test C) in a random order. Time, rating of perceived exertion (RPE), visual analogue scale (VAS) and blood lactate concentrations were measured. **Results**: Mean times of tests A, B and C were 36.19±5.23, 37.03±5.66, and 37.48±6.00 minutes respectively ($p=0.76$). Mean RPE scores after tests A, B and C were 17.65±0.67, 16.95±0.99 and 16.85±0.88 respectively ($p=0.0088$). Mean VAS scores after tests A, B and C were 7.72±0.86, 7.94±0.78 and 8.08±0.69 respectively ($p=0.76$). No differences were found between blood lactate concentrations. **Conclusion**: Acupuncture resulted in significantly higher RPE scores. The clinical significance was that acupuncture lead to higher exertion levels but lower pain scores, which ultimately improved performance (reduced time).

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Chapter One

1.1 Introduction and Problem Statement

Acupuncture originated in China over five thousand years ago, and involves the insertion of fine needles of various lengths into specific points in the body, called acupoints[1]. It is based on the Traditional Chinese Medicine (TCM) belief that health is determined by a balanced flow of qi, the vital life energy present in all living organisms. According to TCM acupuncture theory, qi circulates in the body along twelve major pathways, called meridians, each linked to specific internal organs and organ systems[2]. When needles are inserted into these acupoints, they help correct and rebalance the flow of energy and consequently restore health[3].

TCM concepts of disease are vastly different from the more traditional biomedicine practiced in most countries. However, acupuncture has been explored in relation to western principles of anatomy, physiology and pathophysiology; and clinical experimentation of its effects on these systems have been performed[4-15].

Acupuncture has been reported to be a useful modality in pain reduction of musculoskeletal origin since the mid-70's by Pomeranz[12] and Cheng[7,8]. Pomeranz discovered that through needle stimulation of type I and II afferent nerves, impulses could be sent to higher centers via the anterolateral tract of the spinal cord to promote an endorphin release[16]. Since that time, it has become a very commonly used physical therapy modality for pain relief[13]. Anti-inflammatory effects are commonly

observed with the use of acupuncture as well[17], due to its ability to release local vasopeptides[18] and stimulate the anterior pituitary gland (via the hypothalamus) and cause the release of adrenocorticotrophic hormone (ACTH)[19], both endogenous anti-inflammatories.

Exercise or physical competition at high intensities can induce muscle injury[20]. The body will react to this stress with perceived pain and inflammatory changes, due to the mechanical insult associated with intense and/or repeated muscle contraction[21]. Alleviation or reduction of these symptoms may allow improved performance of an athlete, as they typically cause an impairment in performance[20,22].

Based on the analgesic and anti-inflammatory effects of acupuncture, and the detrimental effects that pain and inflammatory responses have on intense exercise, the aim of this study was to examine acupuncture's acute effects on simulated 20 km stationary cycling performance.

Because the study was designed as a simulated time-trial, and because there are no clearly defined measures in the literature of acupuncture's physiological effects related to ergogenics[11], time to completion of the test was the primary outcome measure, as it directly relates to subject performance. The subject's rating of pain on a visual analogue scale during and after the test was the secondary outcome; while the third measure was the subjects' rating of perceived exertion (RPE), as an increased

RPE rating indicates increased exertion levels[23], which are indirectly related to performance.

As increased lactate thresholds can indicate increased training effects during testing, plasma lactate concentration measurements were also taken as a fourth outcome measure in this study in order to examine this potential (during repeated testing over three weeks). It was also used following testing as an adjunct to the subject's 'level of activity questionnaire' (Appendix A) to assess the nature of the individual's level of fitness.

1.2 Definition of Terms

Acupuncture – Acupuncture is a five thousand year old technique that involves the insertion of fine needles of various lengths into specific points in the body, called acupoints[1]. Its original foundations are based on Traditional Chinese Medicine (TCM) theory. According to TCM acupuncture theory, qi circulates in the body along twelve major pathways, called meridians, each linked to specific internal organs and organ systems[2]. When needles are inserted into these acupoints, they help correct and rebalance the flow of energy and consequently restore health[3].

Visual Analogue Scale (VAS) – The VAS is a subjective measurement tool of pain intensity. It is a self-report instrument consisting of a 10 cm line, anchored on both ends by "no pain" and "pain as bad as it could be". Subjects are instructed to mark on the line their perceived level of pain intensity. A clinician then measures the distance

of the mark from the "no pain" anchor (in millimeters), thus determining the client's level of pain (between 0 and 100)[77]. In this study, the pain experienced in the lower extremities by the subjects will be marked on the VAS scale.

Borg RPE Scale – Perceived exertion is the act of detecting and interpreting sensations arising from the body during physical exercise[60]. The Borg rating of perceived exertion scale consists of numbered (6-20) and corresponding verbal (from "very, very light" to "very, very hard") categories (see Appendix I), and will be used in this study to establish a subjective level of exertion experienced by the subjects during cycle ergometry, due to the intense nature of the test.

Blood Lactate Concentration – During exercise, lactic acid addition to the blood rises in direct proportion to the number of motor fibers recruited and the intensity of the muscle fiber contractions[66]. The blood lactate concentration will increase as work and oxygen consumption increase above the lactate threshold (LT)[71]. In this study the blood lactate concentration is being measured from the fingertip, which is not an entirely accurate measure of blood lactate concentrations in the major vessels of the lower extremities. It is, however, the most convenient method of obtaining a blood sample during testing within the capabilities of the investigator.

1.3 Objectives of Study

The primary objective of this study was to examine the effects of acupuncture on simulated 20km stationary cycling time performance, in comparison to sham/control

sessions among the same subjects. The second objective was to examine if acupuncture could reduce subjective reports of pain and effort during and after a simulated 20km cycling test, using the VAS and Borg scales respectively. The third objective was to examine the relationship between the blood lactate concentrations during and immediately after the test with the other outcomes. Good correlations exist in several studies between Borg RPE scores and blood lactate concentrations[29,31,55,63]. This correlation was also examined among acupuncture, sham acupuncture and control tests.

1.4 Research Hypotheses

The following hypotheses were tested in this study:

1. Acupuncture (test A) will cause a decrease in simulated 20km stationary cycling time, compared to tests B and C.
2. Acupuncture (test A) will cause a decrease in reported VAS and RPE scores immediately after cycling a simulated 20km, and an increase in the blood lactate curve when measured at 5,10,15 and 20km, compared to tests B and C.

1.5 Limitations of Study

1. There was no absolute control over the activities performed or diet consumed by the subjects during the days between tests, beyond the realms of the instruction given by the investigator to maintain a normal routine and the daily activity log kept by the

subjects. This also applies to the amount of sleep each subject received prior to each test and their fatigue levels with each test.

2. Motivation levels between tests in any repeated measures study, especially with one week between tests as was the case in this study, can vary greatly due to many possible external emotional and physical influences. The possibility of this variance was a limitation of this study.

3. Blood lactate concentration was measured via the fingertip and analyzed with a portable blood lactate analyzer. It is unlikely that the blood lactate concentration at the fingertip accurately reflected the blood lactate concentration in the lower extremities. The fingertip was used as a convenience location for sampling during testing, however it was a limitation of the study.

1.6 Delimitations of Study

1. Absolute identical stimulation of both the Test A and Test B acupuncture needles by the investigator for all subjects was attempted but in all likelihood exhibited minor variances due to human error. For example, the 4 Hz stimulation commonly practiced with inserted acupuncture needles is based on the practitioner's simulation of this rate by the motion of his hand on the inserted needle. This is not likely to equal 4 Hz exactly, and not likely to be exactly identical with each needle.

1.7 Ethical Considerations

Acupuncture has been used safely for many years and exhibits almost no side effects or complications when done by a properly trained certified practitioner[13]. It is officially recognized by the World Health Organization as a valid modality for many conditions / impairments[17] and with the general growth in popularity of alternative medicines, its use continues to grow. The most common side effects encountered are mild bruising at the needle site and temporary aggravation of any acute symptoms present during needling[13]. Occasionally, syncope is encountered when a patient is treated in an upright position. However, syncope is a rare occurrence and is immediately relieved with supine positioning[13,17,19].

All subjects in this study were given full disclosure of the potential complications of acupuncture treatment (as is given clinically prior to any acupuncture treatment) and cardiovascular / physical testing (see Appendix L). These latter details can also be found in the consent form (see Appendix M) along with an explanation of the subjects' free participation and right to withdraw from the study at any time without consequence. Subject confidentiality was maintained at all times.

The issue of sham acupuncture often raises issues in blinded acupuncture study ethics. It was used in this study in order to achieve a blinding effect and therefore a more valid study. Valid double-blind acupuncture studies outside of pain control are rare, and in this study, normals were used as subjects (i.e. no subjects were required to endure any impairment or symptoms as a result of participation in the sham

session). Also, the investigator notified all subjects prior to participation that one of the two acupuncture sessions was a "sham" (acupuncture being done safely, away from the regular acupuncture points). A debriefing was given to all subjects following the study as to which session it was. For this reason, it was reasonable to perform sham acupuncture in this experiment.

The subjects underwent constant monitoring during testing by the investigator (PT, Certified by the Acupuncture Foundation of Canada Institute (CAFCI)), with first-aid training and knowledge of the emergency procedures for the building where testing was performed.

This proposal underwent an evaluation from the Health Research Ethics Board (HREB, Panel A) at the University of Alberta before being implemented.

Chapter Two

Literature Review

2.1 The Effect of Acupuncture on Performance

Very little research has been performed regarding acupuncture's effect on ergogenic enhancing measures. Karvelas et al.[24] studied the acute effects of acupuncture on heart rate, RPE and oxygen uptake during graded continuous maximal cycle exercise testing. Ten healthy non-athletic subjects were tested. Cycling began 20 minutes following acupuncture, and the cycling was completed upon volitional fatigue. During testing, heart rate was lower in the control group and highest in the acupuncture group, while RPE scores were lower in the acupuncture group and highest in the control group. However neither of these differences were statistically significant. There was no difference in oxygen uptake during testing among groups.

Ehrlich et al.[25] divided 36 healthy non-athletic males into 3 groups (true acupuncture, sham acupuncture and control), and tested them twice on a cycle ergometer to volitional fatigue, each test being 5 weeks apart. The acupuncture group received a treatment once a week for the 5 weeks between the two tests. At the outset, the subjects in the acupuncture group were able to increase their maximum power output significantly (7.15%W total), and also power output at the anaerobic threshold (6.62% increase in watts at threshold). There was no noticeable effect of acupuncture on the placebo group, while the control group showed lower power outputs following the second test.

Both studies[24,25] used the same acupuncture points (Du20, Liv13, Ren15, Pe6, St36, Sp6, and Ehrlich also adding Bl38), citing Traditional Chinese Medicine theory. Many point combinations for "increased physical performance" can be referenced from various TCM texts[1,2,3,11,17] however little agreement exists between sources. These points vary but in general, include 'qi tonification' and anti-inflammatory acupoints[26]. It is not practical to list all acupoints as they can potentially number in the hundreds, however tonification points are those that are reported to increase the strength and flow of qi[2]. Major examples include Stomach 36 and Spleen 10. Anti-inflammatory points are those that reduce "heat" syndromes, again based on TCM principles[1,2,3], such as Large Intestine 11, Du 14 and Liver 3.

Jaung-Geng et al.[27] investigated the effects of ear acupressure on exercise-induced lactic acid and oxygen consumption levels. Ear acupressure involves the stimulation of ear acupoints with small vaccariae seeds that are taped in place and normally pressed by the subject. Jaung-Geng had 12 healthy untrained male volunteers exercise on a treadmill for 15 minutes, divided into a treatment and placebo group. He noted that lactic acid levels were significantly lower both 5 minutes and 30 minutes post exercise (6% and 14% respectively) in the treatment group. No details were given on any effects this difference had on the performance of the treatment group.

Reaves[28] points to acupuncture's relation to biorhythms (in terms of the TCM concept of yin and yang) to explain its performance enhancing potential. This concept is indirectly related by way of "qi", the representation of energetic and bioelectric / biomagnetic influences on the body. By linking these biorhythms as necessities in psychomotor, physiological and cognitive function in sport, acupuncture is argued to be a useful modality due to its effect on enhancing qi[15,28]. No experimental data was found to support this hypothesis.

Currently, no other study has measured the ergogenic capacity of acupuncture. This study attempted to add to the existing research by providing an objective applicable performance measure (time) in an athletic population performing a fixed-distance simulated time trial. Neither Ehrlich nor Karvelas used trained subjects/athletes, and both utilized a continuous graded exercise protocol to volitional fatigue.

2.2 The Effect of Exercise-Induced Pain on Performance

Muscle soreness during exercise will vary in degree from one type of exercise to another, and from low intensity to high intensity. There is evidence that healthy individuals consistently report experiencing quadriceps muscle pain during moderate and high intensity cycle ergometry[23,29,30,31,32].

Exercises with greater eccentric components, such as cycling[21,33,34,35] tend to cause increased muscle fiber damage and therefore increased pain[20,21]. Structural muscle fiber damage causes the release of noxious chemicals such as histamines,

bradykinins, and prostaglandins; which activate type III and type IV nerve afferents that carry the signals of pain to the central nervous system (CNS)[20,36,37].

Soreness can also result from swelling and intermuscular pressure during exercise. Swelling in the muscle fibers activates free nerve endings within the muscle, contributing to the sensation of peripheral pain, which is then also relayed to the CNS[20].

When the pain signals reach the central nervous system, conscious recognition of the noxious stimulus ensues, and a response to reduce force output usually follows[23,36]. The degree to which this performance reduction occurs is highly dependent on individual perception of pain[22]. Newham et. al. demonstrated that superimposition of electrical stimulation during a maximum voluntary contraction in painful muscle could lead to further production of force, indicating that the reduction in force output was due to subjective pain limitation, not physiological limitations[38].

O'Connor and Cooke[23] demonstrated that increases in perceived pain (using a Borg rating of perceived exertion scale) during cycle ergometry in healthy females (age 20.9±1.7 yrs) corresponded with consistent reduction in power output (21.7W or 15.7%) until test completion (20 minutes). The percentage of VO_{2peak} did not show a statistically significant decline during the drop in power output.

2.3 The Effect of Acupuncture on Pain

The currently accepted hypothesis of acupuncture analgesia is its ability to stimulate the body's endogenous opiates[12], in addition to spinal and supraspinal inhibitory control systems[12,14].

Endorphin is an abbreviation of endogenous morphine, and consists of branched chain amino acid sequences. There are three families of endorphins: enkephalins, dynorphins and beta-endorphins (which contain the largest number of amino acids)[19]. The functions of endorphins involve analgesia, addiction, and homeostasis (regulating hormones, thermoregulation, digestive/cardiovascular and respiratory system regulation)[13,19].

Reversal of pain-relief by narcotic antagonists is a necessary condition to characterize an analgesic manipulation as narcotic[39]. Mayer et al.[40,41] first reported that acupuncture analgesia was reversible in humans by nalaxone (a specific opiate antagonist), implicating an endogenous opioid peptide (endorphin) mediated system that underlies the analgesic effects of acupuncture. Clement-Jones et al.[42] and Chen[43] found that low frequency acupuncture alleviated recurrent pain and significantly increased lumbar cerebrospinal fluid beta-endorphin levels in humans.

These findings were demonstrated following low frequency stimulation of manual or electroacupuncture (4 Hz), which causes an endorphin release from the spinal cord, midbrain, hypothalamus and pituitary. Low frequency stimulation of the acupuncture

needle has also shown slower onset of analgesia, longer duration of effects (cumulative), and as mentioned earlier is blocked by naloxone[41,44].

At a higher frequency (200 Hz), serotonin is more likely to be released; and the analgesic effects exhibit rapid onset, short duration and non-cumulative effects. Both low and high frequency stimulation cause a descending inhibition of spinal cord cells[7,8].

Pomeranz published a comprehensive literature review in 1987 to summarize acupuncture's analgesic effects[16]. Acupuncture needles stimulate A-delta fibers, sending impulses to the anterolateral tract of the spinal cord. From there, messages are sent to one or all three of the spinal cord, the midbrain, or the pituitary-hypothalamic complex. At the spinal cord level, pain is blocked presynaptically by the release of enkephalin and dynorphin, preventing noxious stimuli from ascending the spinothalamic tract. Stimulation of the midbrian (via the periaqueductal grey matter and the raphe nucleus) sends descending signals through the dorsolateral tract, causing the release of the monoamines serotonin (inhibits pain pre- and post-synaptically), epinephrine and norepinephrine in the brainstem and spinal cord. Stimulation in the pituitary hypothalamic complex releases beta-endorphin into the blood stream from the pituitary gland.

These findings support the conclusion that stable physiological changes are evident in a short or long term analgesic effect using acupuncture.

2.4 The Effect of Exercise-Induced Inflammation on Performance

Exercise-induced muscle injury occurs frequently after intense[20,21], unaccustomed[20,45] or high-eccentric load[21,22,45,46,47] exercises. Friden et al. was among the first to demonstrate muscle fiber damage in humans after exercising[48]. One hour after repeated stair descents and cycling exercises, he found that up to 32% of observed fibers showed evidence of structural disturbance. These disturbances were noted as Z-line streaming, loss of thick myofilaments, loss of mitochondria and disturbed arrangement of filaments. This led to the discovery that the initial insult of exercise creates an insult to muscle fibers, which results in damage to the ultrastructure, extracellular matrix, and capillaries[20,21]. This damage activates a local inflammatory response[20,21,45].

Inflammation after muscle injury occurs to clear debris from the stressed area in preparation for regeneration[49]. Activated by the initial mechanical trauma (in this case, exercise), the response is characterized by infiltration of fluid and plasma proteins into the injured tissue, and increases in inflammatory cell populations[50,51]. This proliferation of inflammatory cells is believed to amplify the initial muscle injury during exercise[20,49].

Local inflammatory occurrences and their indirect effects on cellular activity, mechanical efficiency and noxious nerve stimulation of the contractile muscle cells have been noted to reduce performance[20,21,45,52,53]. A recent study by Trappe et al.

used males (25±3 years old) randomized into groups receiving ibuprofen, acetaminophen, and a placebo. Ibuprofen and acetaminophen are systemic anti-inflammatories, acetaminophen also works as an analgesic[53]. The ibuprofen and acetaminophen groups demonstrated statistically significant improvements in performance and completely suppressed inflammatory markers (prostaglandin E, prostaglandin F2 alpha) when compared to the placebo group[52].

2.5 The Effect of Acupuncture on Inflammation

Fewer publications on acupuncture's anti-inflammatory effects exist when compared to its analgesic reports. Much of acupuncture's effects are a result of homeostatic mechanisms[23]. With the release of beta endorphins as mentioned above, there is an equimolar release of ACTH from the pituitary gland, accounting for anti inflammatory responses measured post acupuncture[19].

Electroacupuncture (EA) has been shown to significantly increase blood cortisol in horses when compared to sham EA[9]. Cortisol is a natural steroid hormone produced in the adrenal cortex that has been shown to act as an anti-inflammatory and regulator of blood pressure and metabolism[22].

Lundeberg[18] demonstrated a triggering of vasoactive peptides with acupuncture (substance P and calcitonin gene related peptide - CGRP), which have a wide distribution around sensory nerve endings of peripheral tissues. It has been reported that CGRP can modify the release of inflammatory mediators from mast cells, and

therefore may function as an endogenous anti-inflammatory agent[19]. Due to the effect of local inflammation on performance, acupuncture's anti-inflammatory response may act as an ergogenic aid during intense exercise. Although performance time and subject discomfort will be recorded in this study, there will be no direct measures of inflammatory agents.

2.6 Visual Analogue Scale

The VAS is a subjective measurement of pain intensity experienced during testing. It is a self-report instrument consisting of a 10 cm line, anchored on both ends by "no pain" and "pain as bad as it could be". Subjects are instructed to mark on the line their perceived level of pain intensity. A clinician then measures the distance of the mark from the "no pain" anchor (in millimeters), thus determining the client's level of pain (between 0 and 100)[77].

Test-retest reliability has been recorded between the ranges of 0.71 and 0.99. However, its ability to measure the same construct (pain) as the McGill Pain Questionnaire vary greatly. Wide variances have been noted with the convergent validity (0.30 to 0.95)[77] between these two tests.

2.7 The Borg Scale Rating of Perceived Exertion

The validity of regulating exercise intensity using ratings of perceived exertion has been established[23,54-59]. Perceived exertion has been defined as the act of detecting and interpreting sensations arising from the body during physical exercise[60]. The

principal use of rating of perceived exertion scales is to quantify subjective responses of exercise tolerance[61]; and in this study, the Borg Scale was used to establish a subjective level of discomfort experienced by the subjects during cycle ergometry, due to the intense nature of the test.

The Borg category scale[60] consists of numbered (6-20) and corresponding verbal (from "very, very light" to "very, very hard") categories (see Appendix I). Good correlations exist in many studies between Borg RPE scores and various physiological values (VO2max (0.79-0.92)[35,55,62], blood lactate(0.69-0.88)[29,31,55,63], anaerobic threshold (0.72-0.94)[31,35], heart rate (0.63-0.89)[29,32,55,62]) in trained and sedentary subjects[62,64].

Perez-Landaluce et al.[62] and O'Connor et al.[23] examined the Borg scale in relation to young, amateur, and professional cyclists during cycle ergometry. O'Connor used a Borg scale to indicate quadricep pain levels during testing, and found high correlations between RPE scores and reduction in power output (0.75-0.97 from scores 12-17 on the Borg scale). Perez-Landuce reported fair/good correlations between RPE and: %VO_{2max} (0.79), %maxHR (0.85), and power/kg (0.68), using a 6-20 Borg scale[62].

However, Lamb et al.[64] give low values of test-retest reliability for the Borg scale (0.35 – 0.52) and question its external validity.

2.8 Blood Lacate and Performance

During exercise, lactic acid addition to the blood rises in direct proportion to the number of motor fibers recruited and the intensity of the muscle fiber contractions[66]. The three energy systems of the body include the ATP-PC (phosphagen) system, glycolysis (break down of sugars), and mitochondrial respiration (cellular production of ATP in the mitochondrion)[22]. ATP-PC is the simplest energy system of the body with the shortest capacity to maintain ATP production (approximately 15 seconds)[22]. During short, intense exercise, the phosphagen system is a rapid and available source of ATP.

During submaximal endurance exercise, the energy for muscle contraction comes from regenerated ATP, via mitochondrial respiration, which begins with the same pathway as glycolysis (it is important to note that all three energy systems do not work independently)[67]. Glycolysis converts blood glucose or muscle glycogen into pyruvate[68]. Once pyruvate is produced, it either enters the mitochondria (at an exercise intensity below the lactate threshold) or converts to lactate (when the individual's capacity for mitochondrial respiration is exceeded)[69,70]. The blood lactate concentration will therefore increase curvilinearly as work and oxygen consumption increase above the lactate threshold (LT)[71]. Removal of lactic acid from the blood, meanwhile, will rise as the blood lactate concentration and amount of activity increase[67].

It is at the LT that high-intensity exercise can become compromised. Although the glycolytic and phosphagen systems that are sustaining the continuous output above the threshold can produce ATP at a high rate, they are only capable of doing so for short periods of time[63,72]. This is the point that raises discussion of the lactate response being a more sensitive indicator of endurance performance capacity than ventilatory abilities, as the level at which mitochondrial respiration becomes exceeded can be raised through intense endurance training[44,67,73]. It has been reported that professional cyclists[33,35] and distance runners[65,74] with high lactate thresholds are able to sustain higher power outputs/speeds (respectively) than similarly trained cyclists/runners with equal VO_{2max} levels but lower LT's[67,68,69,70].

2.9 Summary

Acupuncture has been found to be effective in reducing pain[1,2,3,9,13,16-19,39-43] and inflammation[9,13,18,19], symptoms observed during (and reported to be detrimental to the performance of) intense exercise such as cycle ergometry[23,33,62]. The Borg Scale ratings of perceived exertion have been reported to accurately reflect lower extremity effort during cycle ergometry[23], and the VAS is a reliable measure of subjective pain[77]. Due to these reported findings, this study examined if the intervention of acupuncture can affect 20km intense-effort cycle ergometry performance time and test discomfort.

Chapter Three

Methods

3.1 Subjects and Subject Selection

Athletic male subjects (18-30 years) were recruited via convenience sampling of students and general public, for participation in this study. This range was selected as it is commonly the years of highest levels of physical activity among people as well as the beginning of the peak performance ages for a test of this distance and approximate time[22]. Athletic ability was assessed through a questionnaire of time spent in physical activity during the week (see Appendix A). This assessment was done to ensure the subjects regularly took part in physical activity.

The sample size was 20, based on calculations according to treatment study formulae that can be found in Appendix D (alpha = 0.05, beta = 0.20, using time as an outcome measure).

3.2 Subject Recruitment

Recruitment was initiated through poster advertisement (Appendix E) at the University of Alberta Fitness and Lifestyle Center, a private practice physical therapy clinic (Academy Place Physical Therapy, Edmonton) and at the University of Alberta Faculty of Rehabilitation Medicine.

3.3 Inclusion and Exclusion Criteria

3.3.1 Inclusion criteria included:

1. Males between 18 and 30 years of age
2. Previous experience cycling 20km
3. Minimum of 180 minutes of athletic activity per week at the "recreational" level (Appendix A).

3.3.2 Exclusion criteria included:

1. Cardiovascular health problems at the present or in their medical history, as determined by a modified PAR-Q.
2. Any present musculoskeletal symptoms or signs
3. Prior acupuncture experience

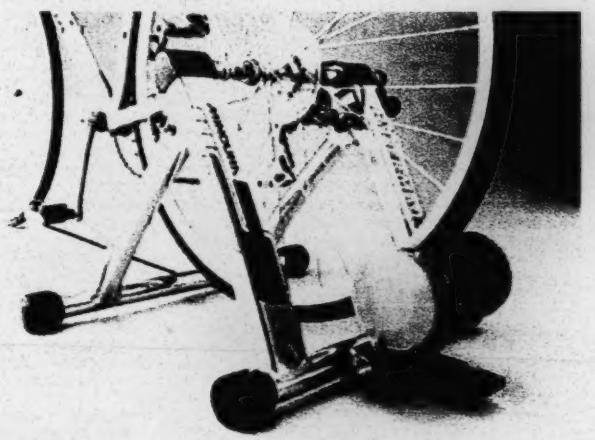
3.3.3 A PAR-Q, modified for those at this level of fitness (see Appendix B), and a physical therapy assessment by the author prior to participation screened exclusion criteria 1 and 2. The physical therapy assessment included a lower extremity range of motion/strength scan and a lumbar scan to ensure no participants had musculoskeletal limitations to performing the tests (Appendix C).

3.4 Test Protocol

This study was a single blind, patient as own control (repeated measures), crossover design. It was performed at the University of Alberta, Faculty of Rehabilitation Medicine.

Subjects underwent three tests, each one a week apart. Every test consisted of riding a road bike mounted on a stationary trainer (Figure 1) for a simulated 20km, as fast as they were able. The cycle used was a Cannondale R600 road bike mounted on a Minoura trainer, and subjects were permitted to change gear ratios as desired throughout the test to maintain the highest speed they could. The computer was a battery-operated unit measuring data from the rear wheel, no plug-in power was connected to the bike and power output was not recorded. Prior to each of these three tests, the participants received one of the following: acupuncture (test A), "sham" acupuncture (test B), or no intervention (control, test C), so that each subject experienced each test condition.

Figure 1. Road bike mounted to rear wheel trainer



The order in which the subjects received the three tests was randomized for each subject (Appendix F), so the possibility of a learning effect would not influence the intervention. This method controlled for a training effect of repeated testing over time, as increased comfort and capability of the test procedure were expected with each test. This was also done to compare the sham acupuncture results with the control findings. Ideally, these tests reflect similar values, whether they are done consecutively or during the first and third tests, and shed more light on the effectiveness of sham acupuncture as a control.

This study involved intense cycling exercise, which may have caused cellular damage to muscle fibers in the lower extremities of the subjects, eliciting an inflammatory response. A normal endorphin response is to be expected with intense exercise[22]. However, it was expected that the centrally mediated endorphin response triggered prior to exercise in the acupuncture test of each subject would hypothetically reveal lower VAS/RPE values due to lower pain levels experienced (when compared to the sham/control tests at the same exercise intensity). This was tested in the hypotheses below.

Subjects were aware prior to testing that one of the acupuncture interventions was a "sham" (due to ethical considerations), however they were not told specifically which session it was until after the experiments were completed.

The outcome measures of each of the tests were:

1) Time to complete a simulated 20km on a stationary cycle (using a chronograph stopwatch). Time to complete 5km, 10km and 15km were also recorded with the other readings (see below).

2) Visual Analogue Scale readings for lower extremity/exercise-induced pain every 5km.

3) Borg (6-20) scale RPE readings at 5km, 10km, 15km and upon finishing at 20km.

4) Blood lactate concentrations at 5km, 10km, 15km and upon finishing at 20km.

Timing of all tests, and questions asked to the subjects for VAS/Borg scale readings (Appendix I), were performed by the investigator using standardized pre-recorded taped prompts to limit rater and measurement bias. Lactate concentration was taken by the investigator at 5km, 10km, 15km and upon finishing at 20km, within 30 seconds of completing the given distance, via a fingertip lancet. Samples were analyzed immediately using a Lactate Pro portable lactate analyzer (Appendix J). Subjects rode a road racing bicycle, loaned by the investigator, mounted on a provided rear-wheel trainer with a distance-counter (computer). All data (four times, four VAS/RPE scores and four blood lactate measures) for each test were recorded on a spreadsheet (Appendix K).

A week passed between tests to eliminate any carryover effects on performance due to fatigue/inadequate recovery[20,75]. Attempts at controlling variables that may have influenced test outcomes (training level, past medical background, age, sex, time of

testing, body composition, activity/diet prior to testing[22]) were made by having acupuncture-naive male subjects with cycling experience tested at the same time of day. They were told to continue with their 'regular' activities and eating habits during this time period between tests, to minimize confounding variables such as varied activities between the tests that may influence the outcomes[22], and to record their diet and activities in a log (Appendix N). Subjects were instructed not to compete in any athletic events during the days between each of the three tests, and to take the day before each test "off" from any physical activity. Also, each subject was used as his own control, with repeated testing.

Acupuncture and lancet sites were cleaned with an alcohol swab and dried completely before needling, and lancet sites were bandaged immediately following blood sample removal. Instructions regarding any potential side effects following testing were also given to all participants as mentioned above. All subjects had access to water during testing; and a sports carbohydrate replacement drink/energy bars immediately following testing, to restore carbohydrate and blood glucose levels that were lost during exercise[22].

3.5 Common Method for Test A and Test B

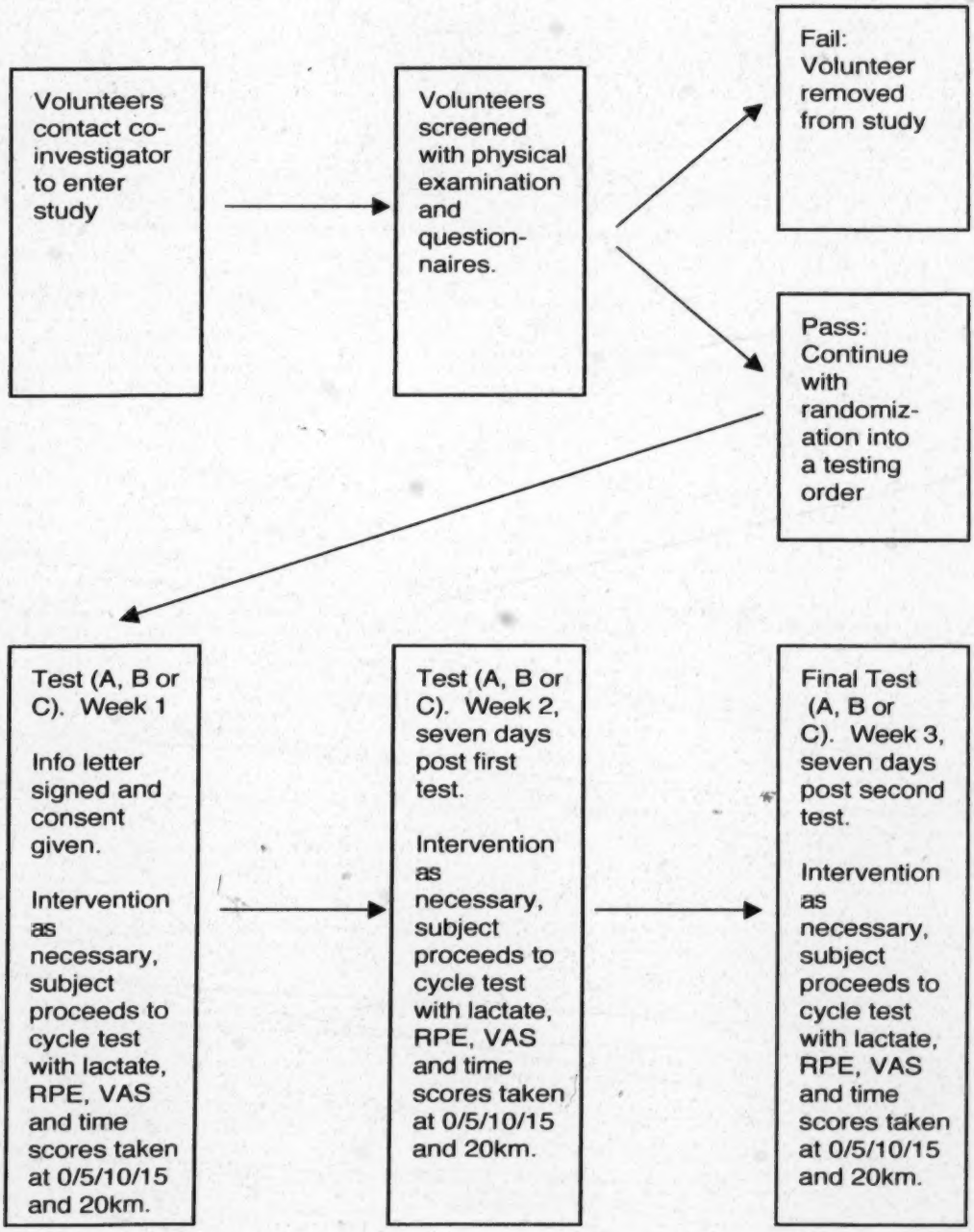
For both Test A and Test B: Needles used were single-use, 0.25x25mm. The researcher wore latex gloves before handling any needles, and began needling once the patient was positioned in supine (see point locations in Appendix G). All disposable needles came in a plastic tube that was approximately 3mm shorter than

the needle, as mentioned above. The tube was placed on the acupoint, and the needle "handle" protruded slightly above it. The handle was tapped quickly to insert the needle, and the tube was then removed. The needle was then manually inserted to the correct depth, and stimulated/retained as required. All needles were removed before exercise. Once the needles were removed, pressure was placed on each acupoint site briefly in the case of minor bleeding with a cotton swab, and then the subject moved immediately to the testing procedure. Needles were disposed of in a portable biohazard sharps container. Testing for all subjects began at 8am on the day of every test. On these days, they were informed to drink only water upon waking and until testing. This was done in an attempt to limit dietary and previous activity influences on test performance[22,67].

3.6 Method Specific to Test A

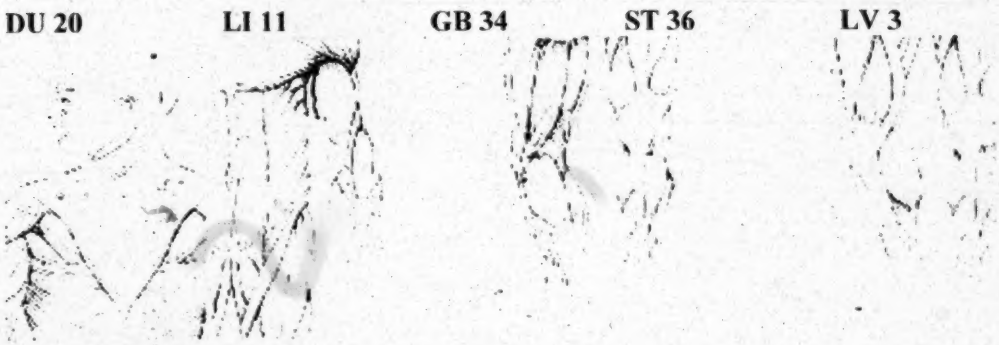
The acupuncture points used and the stimulation time/frequency in test A were based on TCM theory[1,3] and consisted of Stomach 36 (ST36), Gall Bladder 34 (GB34), Large Intestine 11 (LI11), Liver 3 (LV3), and Du Meridian 20 (DU20). All points except for DU20 were needled bilaterally (Figure 2, see Appendix G for exact point locations and needling depths). This study involved manual needle stimulation consistent with TCM acupuncture (unlike electroacupuncture which is necessary to achieve frequencies as high as 200 Hz), and employed an approximate frequency of 2-4 Hz in an effort to stimulate an endorphin response. Needles remained inserted for 20 minutes and were manually stimulated with 180 degree rotation bilaterally at approximately 4 rotations per second every 5 minutes for 1 minute. The investigator

Figure 2. Procedural Method of Study


Volunteers contact co-investigator to enter study
Volunteers screened with physical examination and question-naires.
Fail: Volunteer removed from study
Pass: Continue with randomiz-ation into a testing order
Test (A, B or C). Week 1
Info letter signed and consent given.
Intervention as necessary, subject proceeds to cycle test with lactate, RPE, VAS and time scores taken at 0/5/10/15 and 20km.
Test (A, B or C). Week 2, seven days post first test.
Intervention as necessary, subject proceeds to cycle test with lactate, RPE, VAS and time scores taken at 0/5/10/15 and 20km.
Final Test (A, B or C). Week 3, seven days post second test.
Intervention as necessary, subject proceeds to cycle test with lactate, RPE, VAS and time scores taken at 0/5/10/15 and 20km.

performed the acupuncture and sham acupuncture needling (certified by the Acupuncture Foundation of Canada Institute, the Certificate Program in Medical Acupuncture (Canada) and the Golden Road to Golden Needle (Beijing), Appendix H).

Figure 3. Test A Acupoint Locations



According to TCM, ST36 is a primary qi tonification point, while LV3 promotes free flow of qi[3]. GB34 has a general benefit on the muscles and tendons of the body and to a lesser extent, so does LI11. However, LI11 is reported to have a powerful anti-inflammatory effect as well[3]. DU20 has been proven to increase oxygenation in the brain[2] and is used to improve concentration and focus during intense prolonged activity. All needling was done in a crook lying position (supine with legs bent so feet were flat on bed, supported).

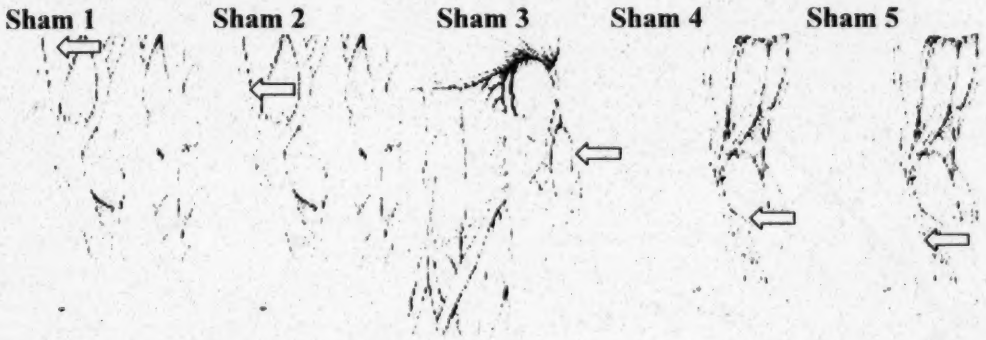
3.7 Method Specific to Test B

The acupuncture points in test B consisted of 5 sham points that did not correspond to any meridian or extra acupoints, and care was taken to ensure that they did not fall

near any of the acupoints selected in test A. A sham acupuncture technique was also used, in which the points were needled bilaterally at a depth of only 2-3mm, retained for 20 minutes. Identical stimulation (needles were manually stimulated with 180 degree rotation bilaterally at approximately 4 rotations per second every 5 minutes for 1 minute) took place as was performed in test A in order to maintain the effectiveness of the sham session.

For the sham treatment, two of the points were on the anterior quadriceps muscle, another on the lateral arm and the last two on the postero-lateral gastrocnemius. See Appendix G for exact point locations. The depth of 3mm was approximated, as this is the average length of needle handle that protrudes superficially in a sterile disposable needle tube. The needle depth was attained by tapping the needle into the sham point, while holding the tube. The tube was then removed (as described in Common Method for Tests A and B) and the needle remained retained at that depth.

Figure 4. Test B Acupoint Locations (Sham acupoints shown by black-outlined arrows, with reference to the closest Test A acupoints used in the test indicated by the white triangles).



3.8 Method Specific to Test C

During this test, the subjects started cycling immediately upon arriving to the testing lab. No acupuncture or sham acupuncture intervention was given, and the testing proceeded as outlined above in 3.4.

3.9 Statistical Analysis

This study involved the collection of descriptive interval data (time of simulated 20km cycle completion), therefore mean and standard deviations were calculated. The second objective consisted of descriptive ordinal data in the form of an RPE rating scale, therefore median and range were analyzed.

Following the experiment; cycling times, VAS and RPE scores were compared between the three tests among all individuals (repeated measures, subject as own control). For this inferential statistic (more than one comparison, more than two groups, unmatched), analysis of variance was run via 3 repeated measures one-way ANOVA's (one for time scores, the second for VAS scores and the third for RPE scores) to determine if the differences among tests A, B and C were greater than would be expected by chance. Post-hoc testing was then performed to specify any significant differences found with the ANOVA's.

A one-way ANOVA was used to compare test A lactate levels with those in test B and separately with those in test C (one test each for comparing test A - test B, and one for test A - test C). An analysis of the order effect of testing was not performed

as all 6 test order combinations were filled almost equally following randomized placement of subjects.

Chapter Four

Results

4.1 Introduction

Twenty acupuncture-naïve male subjects agreed to participate in this study, and completed all components of testing. The mean age for the subjects was 26.3±3.9 years, and all subjects were either semi-competitive or competitive road or mountain cyclists, averaging a mean weekly exercise duration of 212.6±46.7 minutes. Three subjects were randomly allocated into each of the six treatment order combinations, except for the "BCA" and "ACB" orders which received four subjects each due to the random allocation.

The mean values for time, VAS and RPE scores at 20 km (immediately upon completion) for each of the tests are given in Table 1. Overall, cycling times were insignificantly low in the acupuncture group (test A), and high in the control group (test C). The same trend was observed with VAS scores. RPE scores were highest in the acupuncture group and lowest in the control group, and this difference was statistically significant.

4.2 Time

The one way ANOVA performed between groups ($F=3.52$, $df=2,19$, $p=.005$) for the dependent variable of time produced an F value of 0.27, far lower than 1.00 (and the critical value in this experiment of 3.52) resulting in an insignificant time difference

between Tests A, B and C. The critical value for F was based on a $\propto$ value of 0.05, 2 between-groups degrees of freedom and 19 within-groups degrees of freedom.

Table 1: Effects of testing conditions on cycling performance, perceived exertion, lower extremity pain and blood lactate concentrations at 5km, 10km, 15km and upon test completion (20km).

	Acupuncture	Sham Acupuncture	Control	p value
Time to complete 20km (min)	5km: 8.56±2.03 10km: 17.02±2.89 15km: 25.42±3.17 20km: 36.19±5.23	5km: 8.73±2.16 10km: 17.43±3.59 15km: 25.97±3.72 20km: 37.03±5.66	5km: 8.81±2.19 10km: 17.68±3.52 15km: 26.34±3.17 20km: 37.48±6.00	0.76
RPE (6-20)	5km: 12.83±0.89 10km: 15.01±0.79 15km: 16.91±0.72 20km: 17.65±0.67	5km: 12.46±0.87 10km: 14.33±0.99 15km: 15.77±0.72 20km: 16.95±0.99	5km: 12.21±0.64 10km: 14.33±0.99 15km: 15.52±0.85 20km: 16.85±0.88	0.0088
VAS (0-10)	5km: 4.06±0.66 10km: 4.92±0.38 15km: 6.52±0.59 20km: 7.72±0.86	5km: 4.23±0.72 10km: 5.06±0.76 15km: 6.81±0.69 20km: 7.94±0.78	5km: 4.59±0.46 10km: 5.31±0.95 15km: 6.94±0.71 20km: 8.08±0.69	0.35
Blood lactate concen-tration (mmol/L)	5km: 11.21±0.87 10km: 10.57±0.79 15km: 7.64±0.44 20km: 6.96±0.92	5km: 11.13±0.47 10km: 10.46±0.59 15km: 7.37±0.45 20km: 6.51±0.46	5km: 10.92±0.62 10km: 10.41±0.34 15km: 7.34±0.77 20km: 6.39±0.46	0.66

Data are expressed as mean±standard deviations, RPE=rating of perceived exertion, VAS=visual analogue scale.

4.3 Rating of Perceived Exertion

The one way ANOVA performed for the dependent variable of perceived exertion (RPE) produced an F ratio value of 5.15, greater than the critical value of 3.52. Because the calculated value needs to be greater than or equal to the critical F-value to achieve statistical significance, this equals a statistically significant difference between at least two of the three mean RPE scores. The p-value was 0.0088, less than 0.05, meaning there is a less than 5% chance that it is incorrect to conclude this

significant difference. Therefore, a statistically significant difference resulted between tests A, B and C.

RPE scores were highest in the acupuncture group (17.65 $\pm$ 0.67) and lowest in the control group (16.85 $\pm$ 0.88). Post hoc testing of this difference using a Student's T-test among all tests (α=0.05, t=2.002) showed significant differences between both tests A and B (0.156) and to a greater extent between tests A and C (0.256). No significant difference was found between tests B and C (-0.444). This means that the perceived exertion noted by the subjects following testing was only increased with statistical significance with real acupuncture, not with sham acupuncture, which was statistically no different than the control group. It also indicates how acupuncture can be used to notably increase exertion levels beyond those achieved with sham acupuncture and no intervention following intense cycling of 20km.

4.4 Visual Analogue Scale

The one way ANOVA between groups for the dependent variable of lower extremity pain during testing (VAS) produced an F ratio value of 1.06, greater than 1.00 but not greater than the critical F-value in this experiment of 3.52, resulting in an insignificant VAS difference between Tests A, B and C. Therefore, although the lowest VAS scores were noted in the acupuncture group and the highest in the control group, the differences among them are not significant enough that VAS scores could be used as a discriminator. This was also supported by a high p-value of 0.35 (>0.05). Once again, the high p-value (> 0.05) did not allow rejection of the null

hypothesis (any observed differences between tests were due to chance), meaning that acupuncture did not cause a significant decrease in subjective lower extremity pain levels following intense stationary cycling of 20km.

4.5 Blood Lactate Concentration

Blood lactate levels at 5km and 20km displayed a linear decrease during testing with a slope that was statistically insignificant in difference among groups. Neither acupuncture nor sham acupuncture had any effect on the blood lactate levels during or following testing when compared to control testing. Following testing, the one way ANOVA ($F=3.52$, $df=2,19$, $p=.05$) revealed an F-value of 0.42 and a p-value of 0.66, both statistically insignificant. It can be advised that acupuncture will not affect blood lactate levels during or after completing 20km of intense stationary cycling.

Chapter Five

Discussion

The major new finding of this study was that the Rating of Perceived Exertion following exercise in the acupuncture group was significantly higher than the sham and control groups of tests (Table 1). From this it can be concluded that acupuncture was able to consistently and significantly increase the ability of the subjects to exert themselves during testing. The end results of this increased exertion lead to mean time and VAS scores that were lowest in the acupuncture group and highest in the control group. The effects of acupuncture were consistent with the author's hypotheses through these outcomes of time and VAS scores, as well as the lactate concentrations. However the decrease in time and VAS scores in the acupuncture group relative to the sham acupuncture and control groups, and the inverse response with blood lactate concentrations, were not statistically significant. The significantly higher exertion levels reported by the subjects during the acupuncture test resulted in insignificantly improved performance.

The RPE scores highest among the acupuncture group and lowest among the control group counter the study by Karvelas et al.[24], who studied the acute effects of acupuncture on heart rate, RPE and oxygen uptake during graded continuous maximal cycle exercise testing. During his testing, RPE scores were lowest in the acupuncture group and highest in the control group (however the difference was not statistically significant). These differences can be attributed to a few differences between the

studies, such as a twenty minute delay between acupuncture and exercise in Karvelas' study, as well as the graded resistance used, which differs from the simulated race pace in this study. Karvelas also did not use repeated measures and used ten non-athletic subjects, who exercised until volitional fatigue (not a fixed distance test). This is not similar to the repeated measures design of this study which used twenty athletic subjects tested over a fixed distance, at a resistance controlled by the subject to optimize performance.

Although the differences of lactic acid levels between tests in this study were insignificant, they are opposite to the results of Jaung-Geng et al.[27], who investigated the effects of ear acupressure on exercise-induced lactic acid and oxygen consumption levels. Jaung-Geng et al. noted that lactic acid levels were significantly lower both 5 minutes and 30 minutes post exercise (6% and 14% respectively) in the acupuncture treatment group compared to his control. The differences between this study and Jaung-Geng et al.'s could be attributed to the final lactic acid reading being performed immediately following the testing, or even more likely due to the differences in study methodology (repeated measures fixed distance design (greater than thirty minutes) with trained subjects in this study compared to fixed time (15 minutes) exercise performed by untrained subjects in Jaung-Geng et al.'s). The subjects in Jaung-Geng's study were not told to exercise on the treadmill at the most intense level they were able to, unlike this study where this was implicit in the instructions. This difference in exercise intensity is also a likely contributor to the differences in findings.

Regarding the statistically significant increase in RPE values among the acupuncture group of tests, the reduced VAS levels in this study could have lead to a greater output of effort during testing, which was of relatively short duration and high intensity. It could have done this because increased pain levels can reduce physical exertion during intense exercise[22,23,36]. Exercises with high eccentric components, such as cycling[21,33,34,35] cause increased muscle fiber damage and therefore increased pain[20,21]. When pain signals reach the central nervous system, conscious recognition of the noxious stimulus leads to a response to reduce force output[23,36]. The lower but statistically insignificant VAS scores in the acupuncture group may have been an indication of acupuncture's ability to stimulate the body's endogenous opiates[12] and spinal/supraspinal inhibitory control systems[12,14], causing an endorphin release from the spinal cord, midbrain, hypothalamus and pituitary which is known to reduce pain perception[39,40,41,44]. This cannot be claimed with certainty as endorphin levels were not measured in this study.

Therefore the statistically insignificant reduction in lower extremity pain experienced by the subjects during Test A can be assumed to have indirectly created a significant increase in perceived exertion[22,23,36], as the negative effect pain has on exertion was reduced with acupuncture (the subjects were able to cycle harder, increasing their exertion levels, due to decreased lower extremity pain). The increased exertion could therefore have lead to the reduced time during the same test.

The insignificance of the lower VAS scores in Test A was most likely the result of acupuncture's analgesic effects being diluted when followed immediately by intense effort. The frequency of needle stimulation (rotation) attempted during needling mimicked 4 Hz, and low frequency stimulation of acupuncture needles leads to slower onset of analgesia and longer duration of effects (cumulative)[41,44]. Because of the relatively fast testing times (athletic subjects familiar and competent at the distance of 20km) and the study design of exercising immediately post-needling, it may have been more prudent to use high frequency needle stimulation of 200 Hz, which causes serotonin to be released, resulting in rapid onset, short duration and non-cumulative analgesic effects[7,8].

The acupuncture group of tests produced lower cycling times, lower VAS scores, higher blood lactate scores (all statistically insignificant) and higher ratings of perceived exertion (significant) when compared to the sham and control group of tests. The analgesic effect of acupuncture[1,2,3,9,13,16-19,39-43] is a reasonable cause for the lower VAS scores, and the lower pain levels most likely increased physical exertion during the study, as it has been found to do during any intense exercise[22,23,36]. With increased physical exertion, a time reduction and increased lactic acid concentration upon test completion could be expected, and was seen in this study.

Chapter Six

Conclusions

6.1 Introduction

Currently, a major concern among acupuncture practitioners is the lack of research in this field, with respect to any outcomes outside of pain relief, which is not rising proportionately with its increased use[17,76]. This study aimed to provide more experimental data and conclusions on the effects of acupuncture (based on the principles of Traditional Chinese Medicine) on humans, as its potential risks and efficacy must be acknowledged through experimental testing as the practice of acupuncture increases.

A second rationale behind this study was to provide further information on acupuncture as an enhancing agent for human performance. Little evidence exists in the literature of its specific physiological effects, especially over repeated tests, as the few published studies present conflicting results.

6.2 Study Outcomes

A statistically significant difference in rating of perceived exertion was noted between the acupuncture, sham acupuncture and control tests. The acupuncture test resulted in the highest RPE scores, sham acupuncture was second highest and the control group was the lowest. The significant difference lay between the acupuncture group of tests when compared to both the sham and control group of tests.

Regarding the hypotheses of the study, acupuncture caused a statistically insignificant decrease in simulated 20km stationary cycling time, compared to sham acupuncture and the control group. Acupuncture also caused a statistically insignificant decrease in VAS scores for lower extremity pain when compared to sham acupuncture and control testing. No statistically significant differences were found in blood lactate levels between tests, and it can be concluded from this study that acupuncture did not create a change in the blood lactate concentration between tests.

6.3 Clinical Significance of the Results

The increased RPE scores are also clinically significant, as it points to acupuncture's possible ability to promote increased effort in clients during intense exercise without an increased likelihood of detrimental performance. The clinical significance of this study lies in the time reduction of 1.3 minutes between Tests A and C and 0.84 minutes between Tests A and B. Among competitive cyclists riding relatively short distances such as 20km, this time reduction becomes clinically significant. At the 2005 World Time Trial Championships in Madrid, at a distance of 22.1km, one minute separated first place from fifth place.

The motivational and physical results of this over time could be of benefit in rehabilitation programs. The time, VAS and blood lactate concentration differences between groups in this study, although not statistically significant, can be used as feedback to an individual as improvement nonetheless. The decreased pain in the

acupuncture group in this study, even considering its statistical insignificance, was low enough to create increased effort and ultimately increased performance (as shown in the time difference described above). This occurs because once pain signals reach the central nervous system during exercise, conscious recognition of the noxious stimulus will reduce force output and therefore performance[23,36]. If force output can be increased during rehabilitation exercises by reducing the individual's pain, the benefit of these exercises also increases. The increased blood lactate concentrations can also be used as physiological evidence of increased effort, which strengthens the significance of the higher RPE values in the acupuncture group, as lactic acid addition to the blood rises in direct proportion to the number of motor fibers recruited and the intensity of the muscle fiber contractions during exercise[66].

Just as O'Connor and Cooke[23] demonstrated that increases in RPE scores during cycle ergometry in healthy females corresponded with consistent reduction in power output (15.7% over 20 minutes), decreases in RPE can show the opposite effect in symptomatic populations as well. Regardless of impairment, the similarity between cycling 20km or for 20 minutes is that they require effort over a certain amount of time, which is also a constant among all rehabilitation exercises. Perceived exertion, at least on the Borg RPE scale, makes no exceptions for the nature from which the exertion is arising, so decreases in an RPE value following acupuncture can be hypothesized to occur in pathological populations as well.

This study served to support the continued use of acupuncture as an ergogenic aid with respect to its ability to create an increased rating of perceived exertion in the subject.

6.4 Strengths of the Study

Trained subjects were used in this study, which is a strength as the testing technique was specific to the their experiences. The results of this study are also relevant to those who compete in similar cycling events, as the test technique was a simulated time trial, and the results of the study are applicable to an event not limited to a laboratory. A control test was another strength, allowing the investigator to compare acupuncture's effect with a sham (and possible placebo effect) and with no intervention, as well as the differences between a sham acupuncture session and no intervention. In retrospect, the inclusion of sham acupuncture was necessary to highlight that the significant finding of higher perceived exertion in the acupuncture group was a result of the intervention, not of a placebo. The subjects used in this study were acupuncture naïve, and therefore did not have biases based on personal experience on what acupuncture's effects may be, as well as limiting the ability of each subject to differentiate the sham acupuncture session from the real one.

6.5 Weaknesses of the Study

There was no absolute control over the activities performed, diet consumed, or amount of hours slept per night by the subjects during the days between tests, beyond

the realms of the instruction given by the investigator to maintain a normal routine and the daily activity log kept by the subjects. Motivation levels between tests in any repeated measures study, especially with one week between tests as was the case in this study, can vary greatly due to many possible external emotional and physical influences. The possibility of this variance was a weakness of this study. It is unlikely that the blood lactate concentration at the fingertip accurately reflected the blood lactate concentration in the lower extremities. The fingertip was used as a convenience location for sampling during testing. This reading can also be altered with the presence of sweat in the blood sample, and although the investigator attempted to cleanse the area of sweat, it is unlikely that this was done exactly equally with each reading. Identical stimulation of both the Test A and Test B acupuncture needles by the investigator for all subjects exhibited minor variances due to human error.

The gear ratios used by the subjects during cycling were not controlled, each person was instructed to change gears as desired to maintain optimum performance. Although this was done to maintain clinical relevance among cyclists and to more closely simulate a time trial, the variations in these ratios between tests could have affected the outcome measures.

The sample size used was not large enough to compare the outcomes of each test order among themselves (the six possible combinations that were filled with 3 to 4 subjects each) with significant power. The order in which acupuncture was received

may have affected the degree to which it provided anti-inflammatory, and thus performance enhancing, effects. Those subjects who cycled twice before receiving real acupuncture could theoretically stand to benefit the most from it.

6.6 Directions for Future Research

Specific to this study, other possible future research directions could include using the same interventions in a larger sample size of athletes immediately prior to a major race, and analyze its effects among an extremely homogenous population with similar motivation levels. It is the investigator's hope that the conclusions drawn from this study will spur research into using acupuncture to increase physical exertion, and performance as a result, in pathological populations. When pain, whatever its source, can be reduced enough to enable an individual to increase their effort during rehabilitative exercise, the possibility for functional improvement also increases.

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Appendix A

Subject Activity Level Questionnaire and Past Medical History Screen

Please answer the following, using the back if extra space is required:

1. On average, how many days are you involved in physical activity during the week?

2. On average, how long do you perform physical activity during these given days (in minutes)?

3. Please give details as to what physical activity you are currently involved in, how long you have been doing it and at what level do you do it (recreational, semi-competitive, competitive).

4. Do you have any current or history of previous injury or disease? If so, please elaborate in detail, including any allergies.

Your amount of physical activity per week will be found by multiplying #1 and #2. A minimum value (which you won't be told) will be what decides whether you can participate in the study.

Appendix B

Modified PAR - Q

Common sense is your best guide when you answer these questions. Please read the questions carefully and answer each one honestly: Anser **YES** or **NO**

1. Has your doctor ever said that you have a condition and that you should only do physical activity recommended by a doctor?
2. Do you feel pain in your chest when you do physical activity?
3. In the past month, have you had chest pain when you were not doing physical activity?
4. Do you lose your balance because of dizziness or do you ever lose consciousness?
5. Do you have a bone or joint problem that could be made worse by a change in your physical activity?
6. Is your doctor currently prescribing drugs for any condition?
7. Do you know of **any other reason** why you should not do physical activity?

If you answered yes to one or more questions:
Talk with your doctor by phone or in person BEFORE you participate in a fitness test. Tell your doctor about the PAR-Q and which questions you answered YES.

If you answered NO honestly to all PAR-Q questions, you can be reasonably sure that you can:
Take part in a fitness test

DELAY BECOMING MUCH MORE ACTIVE:
If you are not feeling well because of a temporary illness such a cold or a fever - wait until you feel better.
Please note: If your health changes so that you then answer YES to any of the above questions, tell the experiment tester.
Note: If the PAR-Q is being given to a person before he or she participates in a physical activity program or a fitness appraisal, this section may be used for legal or administrative purposes.

I have read, understood and completed this questionnaire. Any questions I had were answered to my full satisfaction.

_____ _____

print name and date signature

_____

witness signature

Appendix C

Lower Extremity / Lumbar Scan Form

To be performed prior to participant testing as a physical therapy screen, any positive findings may exclude participant from study.

Lspine and Lower Extremity AROM/PROM:

Lspine PIVM's:

Lumbar scan (myotomes, dermatomes, reflexes):

Squat test-

SLR-

Heel raises-

Prone Knee bend-

SI compression/distraction-

Other Findings-

Appendix D

Power and Sample Size Calculations

- hypothesized average time for Test A: 30 minutes
- hypothesized average time for Test B: 32 minutes
- Average time for Test C: 35 minutes[20]
- grand mean = 32.33 minutes, SD = 2.5 minutes[20]

$-S_m = \sqrt{((\sum x_i - x_g) / k)} = \sqrt{[(30 - 32.33)^2 + (32 - 32.33)^2 + (35 - 32.33)^2]} / 3 = 1.18$
$- f = S_m / S = 1.18 / 2.5 = \textit{0.47}^*$

Sample sizes needed for the analysis of variance for $\alpha = 0.05$:

		f *0.5**
$df_b = 2$	0.7	11
	0.8	14
	0.9	**18**

Value rounded up to 20 subjects total, as all subjects receive acupuncture in one of their three tests.

Power of the F-Test in ANOVA for $\alpha = 0.05$, $df_b = 2$:

n	f *0.5**
18	90
19	92
20	**93**

Therefore, we can estimate that power is approximately 93% for a sample size of 20.

Appendix E

Recruitment Poster

See next page for exact copy of recruitment poster as it appeared when posted.

Volunteers Needed for Study:

Effect of Acupuncture on 20km Cycling Performance

Healthy active male cyclists between the ages of 18 and 30 are required for a study involving acupuncture and its effects on physiological and subjective measures of performance.

The study consists of three sessions one week apart, each lasting approximately 120 minutes, performed by a physical therapist with acupuncture certification. You will be required to cycle a simulated 20km on a stationary bike at "race pace" (as fast as you can) during each session, and carry on with your normal activities and diet in the days between tests.

Blood lactate measurements will be taken with a fingertip "lancet" (needle) during (four times) and after (one time) each test. Acupuncture involves the insertion of small, thin needles into certain points on the body. It is most often described as painless and is very safe when done by a certified practitioner. Needles will only be left in for 15 minutes and will be used for two of the three sessions. In this study, 7 points will be used during two of the three sessions. They are located on the outside of the elbows, 2 below the knees, on top of the feet, and on top of the head.
One of the sessions will involve a "sham" acupuncture session, in which you will receive safe needling on sites that do not correlate to actual acupoints.

Refreshments will be provided following all sessions, which will be held in the morning (8am), at the University of Alberta, Faculty of Rehabilitation Medicine (Corbett Hall).

For more information please contact Sat Dhillon PT / CAFCI at satpal@ualberta.ca (780-492-5765). Your participation is greatly appreciated. Thank you.

Appendix F
Randomization Procedure

Participants all underwent the same interventions before the three tests (test A, B or C), however they did so in a randomized order. Subjects were tested one at a time. As a subject entered the study, they picked a 5 series number from the random table below. The first number in the series of 5 digits that lay within 1-6 (inclusive) was the testing order they received (based on the following order): 1=ABC, 2=ACB, 3=BAC, 4=BCA, 5=CAB, 6=CBA. *For example, if a subject picked "91465", they were in test 1 (ABC), as 1 is the first digit from 1-6 that appears in the series going from left to right.* Each subject was given an unmarked table and numbers remained in the table after being picked by others.

39634 62349 74088 65564 16379 19713 39153 69459 17986 24537
14595 35050 40469 27478 44526 67331 93365 54526 22356 93208
30734 71571 83722 79712 25775 65178 07763 82928 31131 30196
64628 89126 91254 24090 25752 03091 39411 73146 06089 15630
42831 95113 43511 42082 15140 34733 68076 18292 69486 80468
80583 70361 41047 26792 78466 03395 17635 09697 82447 31405
00209 90404 99457 72570 42194 49043 24330 14939 09865 45906
05409 20830 01911 60767 55248 79253 12317 84120 **77772** 50103
95836 22530 91785 80210 34361 52228 33869 94332 83868 61672
65358 70469 87149 89509 72176 18103 55169 79954 72002 20582
72249 04037 36192 40221 14918 53437 60571 40995 55006 10694
41692 40581 93050 48734 34652 41577 04631 49184 39295 81776
61885 50796 96822 82002 07973 52925 75467 86013 98072 91942
48917 48129 48624 48248 **91465** 54898 61220 18721 67387 66575
88378 84299 12193 03785 49314 39761 99132 28775 45276 91816
77800 25734 09801 92087 02955 12872 89848 48579 06028 13827
24028 03405 01178 06316 81916 40170 53665 87202 88638 47121
86558 84750 43994 01760 96205 27937 45416 71964 52261 30781
78545 49201 05329 14182 10971 90472 44682 39304 19819 55799
14969 64623 82780 35686 30941 14622 04126 25498 95452 63937
58697 31973 06303 94202 62287 56164 79157 98375 24558 99241
38449 46438 91579 01907 72146 05764 22400 94490 49833 09258
62134 87244 73348 80114 78490 64735 31010 66975 28652 36166
72749 13347 65030 26128 49067 27904 49953 74674 94617 13317
81638 36566 42709 33717 59943 12027 46547 61303 46699 76243
46574 79670 10342 89543 75030 23428 29541 32501 89422 87474
11873 57196 32209 67663 07990 12288 59245 83638 23642 61715
13862 72778 09949 23096 01791 19472 14634 31690 36602 62943
08312 27886 82321 28666 72998 22514 51054 22940 31842 54245
11071 44430 94664 91294 35163 05494 32882 23904 41340 61185
82509 11842 86963 50307 07510 32545 90717 46856 86079 13769
07426 67341 80314 58910 93948 85738 69444 09370 58194 28207
57696 25592 91221 95386 15857 84645 89659 80535 93233 82798
08074 89810 48521 90740 02687 83117 74920 25954 99629 78978
20128 53721 01518 40699 20849 04710 38989 91322 56057 58573
00190 27157 83208 79446 92987 61357 38752 55424 94518 45205
23798 55425 32454 34611 39605 39981 74691 40836 30812 38563
85306 57995 68222 39055 43890 36956 84861 63624 04961 55439
99719 36036 74274 53901 34643 06157 89500 57514 93977 42403
95970 81452 48873 00784 58347 40269 11880 43395 28249 38743
56651 91460 92462 98566 72062 18556 55052 47614 80044 60015
71499 80220 35750 67337 47556 55272 55249 79100 34014 17037
66660 78443 47545 70736 65419 77489 70831 73237 14970 23129
35483 84563 79956 88618 54619 24853 59783 47537 88822 47227
09262 25041 57862 19203 86103 02800 23198 70639 43757 52064

Example 2: If a subject picked 77772 they were in test 2 (ACB). If a 5 digit number was selected without any of the numbers 1-6, they were asked to choose again.

Appendix G

Acupoint Locations and Needling Depths

Acupuncture Session

ST36 - Located below the knee, one cun (subject D1 finger-breadth) lateral to the anterior crest of the tibia, 3 cun inferior to ST35. Perpendicular needle insertion 2 cm bilaterally.

GB34 - Below the lateral aspect of the knee, in the depression 1 cun anterior and inferior to the head of the fibula. Perpendicular needle insertion 2 cm bilaterally.

LI11 - At the elbow, midway between LU5 (lateral border of the bicipital tendon at the flexor elbow crease) and the lateral epicondyle, at the lateral end of the transverse cubital crease). Perpendicular needle insertion 2 cm bilaterally.

LV3 - On the dorsum of the foot, in the space immediately distal to the junction of the first and second metatarsals proximally. Perpendicular insertion 1 cm bilaterally.

DU20 - midline of the scalp, 5 cun posterior to the anterior hairline (or 8 cun post. to the glabella) and 7 cun superior to the posterior hairline (or 6 cun superior to the external occipital protuberance). Needle transversely forwards along the midline 1.5 cm.

Sham Acupuncture Session

Sham 1 - anterior midline along rectus femoris, 6 inches proximal to superior border of patella in knee extension. 2 - 3 mm perpendicular insertion bilaterally.

Sham 2 - anterior midline along rectus femoris, 8 inches proximal to superior border of patella in knee extension. 2 - 3 mm perpendicular insertion bilaterally.

Sham 3 - 3 cun inferior and 2 cun lateral to the lateral epicondyle in the anatomical position. 2 - 3 mm perpendicular insertion bilaterally.

Sham 4 - posterolateral aspect of the lateral gastroc head, 10cm below lateral end of popliteal crease. 2 - 3 mm perpendicular insertion bilaterally.

Sham 5 - posterolateral aspect of the lateral gastroc head, 3 cm below sham 4. 2 - 3 mm perpendicular insertion bilaterally.

Appendix H

Certification of Writer

The Acupuncture Foundation of Canada Institute

SATPAL DHILLON, B.Sc PT, CAFCI

[illegible] the appropriate post-graduate study required by the Education Committee of The Acupuncture Foundation of Canada Institute and having successfully completed the

AFCI Examination in Acupuncture is awarded this certificate

[illegible]

[illegible]

Director of Education

THE UNIVERSITY OF ALBERTA

CERTIFIES BY THIS DOCUMENT TO ALL WHOM IT MAY CONCERN THAT

SATPAL DHILLON

HAVING SATISFACTORILY COMPLETED ALL THE STATUTORY REQUIREMENTS
HAS BEEN GRANTED THE DEGREE OF

BACHELOR OF SCIENCE IN PHYSICAL THERAPY

AND AWARDED ALL THE RIGHTS AND PRIVILEGES PERTAINING TO THIS DEGREE.

IN TESTIMONY WHEREOF ARE AFFIXED THE SIGNATURES OF THE CHANCELLOR
THE CHAIR OF THE BOARD OF GOVERNORS, THE PRESIDENT, AND THE REGISTRAR
OF THIS UNIVERSITY TOGETHER WITH THE COMMON SEAL OF THE SAME.

GIVEN AT THIS UNIVERSITY ON THE 8TH DAY OF JUNE,
ONE THOUSAND NINE HUNDRED AND NINETY-EIGHT
IN THE NINETY-FIRST YEAR OF THE UNIVERSITY OF ALBERTA

CHANCELLOR

PRESIDENT

REGISTRAR

ASSISTANT SECRETARY-GENERAL

UNIVERSITY OF ALBERTA

FACULTY OF EXTENSION

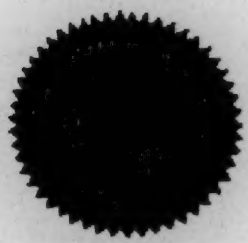
[illegible] document is to certify that

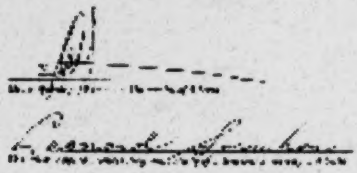
Satpal Singh Dhillon

has completed a Program of Studies leading to the certificate in

Medical Acupuncture

at Edmonton on the 15th day of June, 2000

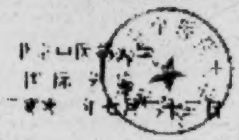




证 书

兹有加拿大 Satpal Dhillon 先生于二零零一年六月二十二日至二零零一年七月二十三日在北京中医药大学国际学院参加了针灸专业课程的学习。

This is to certify that Mr. Satpal Dhillon from Canada has participated in the Acupuncture training course from June 22nd 2001 to July 23rd 2001 at International School of Beijing University of Chinese Medicine.



International School
Beijing University of Chinese Medicine
Date: July 23rd 2001 Ser.No. BUCM(2001)072

Appendix I

BORG SCALE OF PERCEIVED EXERTION

6	
7	Very, Very Light
8	
9	Very Light
10	
11	Fairly Light
12	
13	Somewhat Hard
14	
15	Hard
16	
17	Very Hard
18	
19	Very, Very Hard
20	

Appendix I cont.

Questions Asked to Subjects to Prompt an RPE Report During/Post Testing

Before the test, subjects were informed that a 6 on the Borg Scale is the equivelant rating of exertion required to get out of bed in the morning, while a 20 is the equivelant rating of being physically unable to continue testing after reaching the highest level of output the individual is capable of. It should not be possible for the subject to continue the test when reporting a 20.

After the simulated 20km cycling session; and at the 5, 10 and 15km marks, the following prompt was used to determine a rating of exertion. It was played on a portable stereo, pre-recorded by the writer.

-"Please rate your present level of exertion using a number on the scale in front of you".

The Borg Scale was visible to the subjects when they were being prompted.

Questions Asked to Subjects to Prompt a VAS reading During/Post Testing

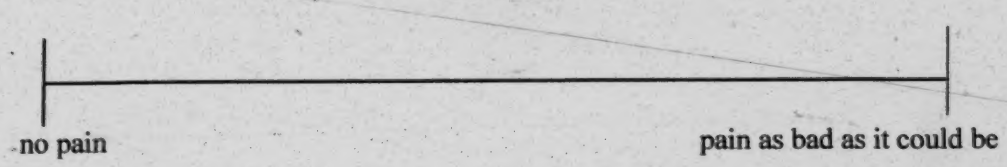
Before the test, subjects were informed of the two anchors on the VAS (no pain, pain as bad as it could be), and that it should not be possible to continue the test if marking the latter anchor.

After the simulated 20km cycling session; and at the 5, 10 and 15km marks, the following prompt was used to determine a VAS reading. It was played on a portable stereo, pre-recorded by the writer.

-"Please rate your present level of pain by making a mark along the scale in front of you"

The VAS was visible to the subjects when they were being prompted, it was laminated and the subject was briefly handed a non-permanent pen to mark the scale (this was then wiped off by the examiner once the data was recorded).

VAS Scale

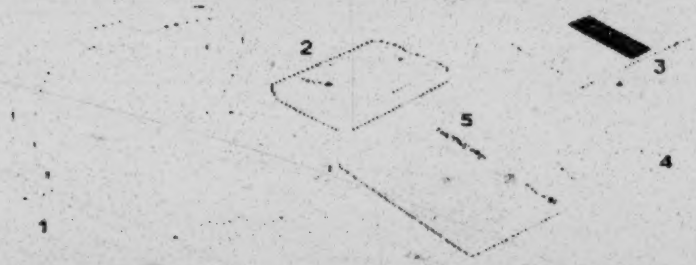


Appendix J
Blood Lactate Lancet and Analyzer Details

In this study a 'Lactate Pro' portable lactate analyzer was used during and immediately following testing for instant measures of blood lactate concentration, in a designated WHMIS lab. Latex gloves were worn during all procedures, and lancets were disposed of in a portable biohazard sharps container. The following information is taken from the website www.fast-canada.com, manufacturers of the unit.

Lactate Pro adopts the electrochemical measurement method utilizing enzyme reaction. The operation has been further simplified. As little as 5 microL (approximately 2mm diameter drop) of blood is enough for a measurement. Furthermore, the wiping of excess blood and other troublesome preparation are not required. Measurements are completed in a mere 60 seconds. The automatic aspiration of blood greatly reduces the risk of human error, and thus provides accurate blood lactate level without involving any manual operation.

The Lactate Pro test system is the only Lactate measurement system to achieve Waived Status under the US FDA Clinical Laboratory Improvement Amendments. In the regulations, waived tests are defined as simple laboratory examinations and procedures that are cleared by the Food and Drug Administration for home use; employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible.



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Electrochemical Assay System with Single-Use Electrode Strip for Measuring Lactate in Whole Blood

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We have developed an assay system for measuring lactate in whole blood, consisting of a single-use strip of an enzyme-coated electrode and a small meter. The electrode strip is made of three plastic films: a cover sheet, a spacer, and an insulation layer printed with electrodes that are coated with lactate oxidase (EC 1.1.3.x) and ferricyanide as an electron mediator. The meter measures the magnitude of the anodic current of the reduced mediator by the enzymatic reaction and displays the lactate concentration 60 s after a blood sample (5 mL) is applied. The calibration curve was linear up to 20 mmol/L, and the between-run CVs at three concentrations were 1.7-8.4%. Lactate concentrations determined by this method (y) in blood samples from healthy individuals before and after exercise agreed with the results obtained by the conventional enzymatic method (x): $y = 0.97x - 0.3$, $Sylx = 0.7$. This assay provides a rapid and convenient test for measuring blood lactate concentrations.

Indexing Terms: enzymatic method point-of-care testing. lactate oxidase

Lactate concentration in blood is a biochemical indicator of anaerobic metabolism in patients with circulatory failure. When the blood flow is markedly decreased, oxygen delivery is no longer adequate to sustain aerobic metabolism, creating an oxygen debt. The concentration of lactate in blood

corresponds to the extent of the oxygen deficit, and measurement of blood lactate gives information for diagnosis and estimation of a prognosis in affected patients (1). Blood lactate concentrations increase during physical exercise, and the changes in these concentrations are useful for estimating physical fitness and the effects of exercise (2, 3). An electrode analyzer with an enzymatic sensor can measure lactate concentrations in whole blood and overcomes the limitations of conventional enzymatic assays, which are time-consuming and technically complex (4, 5). We developed an assay system for measuring lactate concentrations in whole blood that includes a single-use strip of an enzyme-coated electrode and a small meter containing a data processor. We used this system to study blood samples from healthy individuals before and after exercise, and here we report our results.

Materials and Methods

Reaction principle. The following schema, where LODox and LODred represent oxidized and reduced lactate oxidase, respectively, describes the reaction sequence.

Lactate + LODox ‡ pyruvate + LODred (1)

LODred + [Fe(CN)6]3- ‡ LODox + [Fe(CN)6]4- (2)

[Fe(CN) 6]4- ‡ [Fe(CN) 6]3- + e- (3)

Reactions 1 and 2 occur simultaneously. Lactate in the blood is specifically oxidized by LODox to pyruvate; LODox is reduced to LODred. LODred is oxidized with ferricyanide, an electron mediator, to LODox, which again oxidizes lactate. Thus LOD repeatedly oxidizes lactate and changes the mediator to the reduced form, ferrocyanide. The accumulated ferrocyanide is finally oxidized to ferricyanide, as shown in equation 3, by an electrode with a potential of +0.5 V. The anodic current is measured by an amperometer.

Electrode strip. A 24 x 6 mm strip was made of three plastic films: a cover sheet, a spacer, and an insulation layer. A reaction layer was formed on the carbon electrodes, which were printed on the insulation layer (Figure 1). The reaction layer was cast and dried from 2 mL of 5 g/L carboxymethyl cellulose (Dai-ichi Kogyo Seiyaku Co., Kyoto, Japan) containing 1.6 U of lactate oxidase (EC 1.1.3.x) from *Pediococcus sp.* (Asahi Chemical Industry Co., Shizuoka, Japan) and 50 mmol of tripotassium hexacyanoferrate (Nacalai Tesque, Kyoto, Japan). About 5 mL of whole blood aspirated by capillary action into the open end of the spacer moved into the space between the three films.

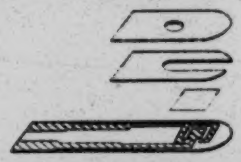

Figure 1: Schematic of the single-use electrode strip

Meter. The GlucocardR blood glucose meter (Kyoto Dai-ichi Kagaku Co., Kyoto, Japan) (6) was modified for lactate measurements. The potential (+0.5 V) was applied 55 s after sample introduction, and the magnitude of the anodic current was measured instantaneously by the meter. The meter was powered by two lithium batteries. The size of the meter was 86 x 53 x 13 mm; its weight was 50 g. The data processor in the meter calculated the lactate concentration from the current by using a programmed calibration curve, and the value was displayed. The meter has a thermosensor and a program to decrease the effect of temperature on measurements.

Procedure. An electrode strip was inserted into the strip inlet of the meter, and the meter switched on automatically. When the other end of the strip touched a drop of whole blood, about 5 mL was aspirated and measurement started. The lactate concentration was displayed after 60 s; the meter turned off when the strip was removed. The used strip was discarded.

Comparison method. We also measured lactate concentrations in blood samples with a kit (Determiner LA; Kyowa Medix, Tokyo, Japan). The analysis was based on the conversion of lactate to pyruvate and hydrogen peroxide by lactate oxidase in the presence of oxygen. The generated hydrogen peroxide reacts with the chromogens 4-aminoantpyrine and N-ethyl-N-(3-methylphenyl)-N'-acetyl ethylenediamine, catalyzed by horseradish peroxidase. Absorbance was measured at 415/550 nm with a Hitachi 7150 analyzer (Hitachi, Tokyo, Japan).

Blood sampling. Blood samples were obtained from 10 healthy volunteers before, during, and after exercise on an ergometer, and the workload was increased gradually until the individuals reached exhaustion. Before beginning the study, we obtained informed consent from all participants.

Immediately after blood sampling, we assayed the concentrations of lactate with our system; another portion of the blood sample was treated with perchloric acid and assayed by the comparison method.

Results

The lower limit of detection by this new method was 0.1 mmol/L The calibration curves for lactate concentrations in whole blood and plasma were linear up to 20 mmol/L (Figure 2).

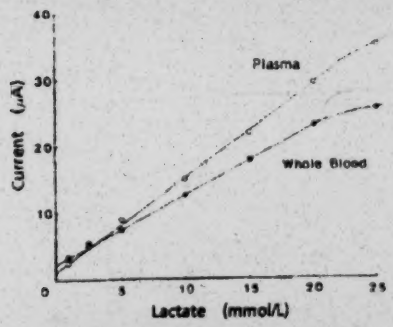

Figure 2: Calibration curves in whole blood and plasma

Table 1 shows that the assay precision for blood samples with lactate, assayed 10 times each, is 1.7 – 8.4% (CV).

During this procedure, sodium fluoride was added (24 mmol/L) to inhibit lactate production; this concentration had no effect on the assay procedure and was sufficient to inhibit the increase in blood lactate for 3 h. Heparin was added as an anticoagulant. Glucose at a final concentration of 44.4 mmol/L, creatinine at 884 mmol/L, uric acid at 1190 mmol/L, bilirubin at 137 mmol/L, glutathione (reduced form) at 1.3 mmol/L, acetaminophen at 1.0 mmol/L, sodium salicylate at 2.0 mmo/L, glycerate at 2.0 mmol/L, and 3-hydroxybutyrate at 3.5 mmol/L had a negligible effect on the results of the blood lactate measurement. Addition of ascorbic acid at a final concentration of 1.14 mmol/L caused a 37% increase in the results.

Table 1: Precision of the Electrode Strip Method

	Mean ± SD, mmol/L	CV, %
Sample A	0.94 ± 0.08	8.35
Sample B	3.50 ± 0.06	1.67
Sample C	8.63 ± 0.23	2.65 n = 10 each

We examined the effect of hematocrit on the assay by measuring lactate concentrations in samples with different hematocrit values (Figure 3).

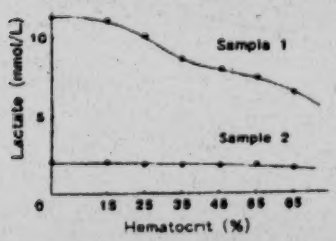

Figure 3: Effect of hematocrit on measured lactate values

Two blood samples with different lactate concentrations were assayed by the procedure described in the text

The samples were prepared by separating plasma and erythrocytes in the presence of heparin and sodium fluoride, then mixing them again to produce the desired hematocrit. In sample 1, with a high lactate concentration, the lactate values in the low-hematocrit samples were higher than those in a normal-hematocrit sample; the lactate values in samples with a high hematocrit were even lower. In sample 2, with a low lactate concentration, the measured values were little affected by differences in hematocrit. The correlation between lactate concentrations in 80 blood samples from the individuals before, during, and after exercise, measured by the eleetrode strip method (y) and by the comparison method (x), which is the usual method in Japan, was $r = 0.976$ (y = 0.966x – 0.254 mmo/L, $Sylx$ = 0.678 mmol/L).

Discussion

An electrode analyzer with an enzymatic sensor that can measure lactate concentrations directly in whole blood offers the advantage of easy handling of samples without the need for immediate deproteinization and centrifugation (4, 5). The test-strip method also provides rapid and precise measurements of lactate concentrations in whole blood (7). An amperometric assay of blood glucose with a ferrocene-mediated enzyme electrode has been developed and used to assay blood glucose with a single-use electrode strip (6, 8, 9). The conventional meters for glucose self-monitoring have glucose oxidase strips that change color. The disadvantages of these systems are that the user has to perform the test in a precisely timed cycle, and the blood-stained end of the strip that is inserted into the meter may contaminate it and cause inaccurate measurements. The assay system for measuring blood glucose with a single-use electrode strip resolves these issues.

Our assay system for measuring blood lactate also has a single-use electrode strip. The calibration curve for blood lactate was linear up to 20 mmol/L, which exceeded the maximum concentrations of blood lactate after exhaustive exercise. The required sample volume was 5 **mL** of whole blood, which seems particularly appropriate for use in obstetric and neonatal intensive care. In sports medicine, the use of a lancet for blood sampling makes it possible for coaches or athletes to measure blood lactate concentrations without the help of a doctor or a nurse. The new method is easy to operate, and the results are available in 60 s. The correlation between the lactate concentrations measured with the strip and the kit was high. In samples with a high lactate concentration, the lower the hematocrit, the higher the displayed lactate concentration. This result suggested that lactate concentrations in plasma samples could not be measured with this system. However, we observed a linear relation between the lactate concentrations in plasma and the magnitude of the electric current generated (Figure 2). The correct lactate concentrations in plasma were obtained when the concentrations were calculated with another calibration curve for plasma lactate measurements.

The new assay system is a rapid, convenient, and reliable method for measuring lactate concentrations in whole blood, and the meter itself is pocket-sized. These characteristics allow lactate to be measured at the bedside, in the laboratory, and even outdoors for application in clinical and sports medicine.

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Appendix K
Subject Information Sheet

Spreadsheet of each subject's name, age, weight, and test time, VAS/RPE and blood lactate of each of the three tests for each subject (1st, 2nd or 3rd circled to indicate randomized group placement order).

Subject: Age: Weight: Time of test:	Time	VAS	Borg	Lactate
Test A (1^{st} 2^{nd} 3^{rd})	5km- 10km- 15km- 20km-	5km- 10km- 15km- 20km-	5km- 10km- 15km- 20km-	5km- 10km- 15km- 20km-
Test B (1^{st} 2^{nd} 3^{rd})	5km- 10km- 15km- 20km-	5km- 10km- 15km- 20km-	5km- 10km- 15km- 20km-	5km- 10km- 15km- 20km-
Test C (1^{st} 2^{nd} 3^{rd})	5km- 10km- 15km- 20km-	5km- 10km- 15km- 20km-	5km- 10km- 15km- 20km-	5km- 10km- 15km- 20km-

Appendix L
Information Letter

The Effect of Acupuncture on 20km Cycling Performance

Primary Investigator: Dr. David Magee, PT, PhD
Co-Investigator: Satpal Dhillon, BScPT, MScPT student

Background: Acupuncture is a treatment technique used by many clinicians, primarily to treat pain. There are a small number of acupuncturists who feel it can have positive performance effects with athletes during competition, but there is little to support this.

Purpose: The purpose of this study is to find out what effect acupuncture has on your athletic performance.

Procedures:
a) Three tests will be performed (one week apart), where you may or may not receive acupuncture before being tested. Each test will begin at 8am.

b) Testing will involve cycling a simulated 20km on an indoor stationary bike, at race pace. Measurements of how hard you are cycling will be taken by different methods. The first is simply timing how long you take to complete 20km on a stationary cycle. The second is rating how tired you are on a scale graded from 6 – 20 (Borg Scale of Perceived Exertion), and how much pain you feel on a visual scale, where you will mark on a line indicating how much pain you feel ranging from 'no pain' to 'pain as bad as it could be'. Both scales will be posted in front of you to mark during and following the test. A third measurement will also be taken to determine how much your blood lactate levels rise during testing. This will involve pricking your finger five times to take a small drop of blood from the tip of the finger. These blood samples will all be taken at 0, 5, 10, 15 and 20km.

You will be asked to drink only water before coming to the test. You will have access to water during the test. Each test should take no longer than 120 minutes, preparation included.

All tests will involve the same measurements. However, before two of the three tests, you will receive a 20 minute acupuncture treatment. Acupuncture is a safe technique and will be performed by a qualified physical therapist. It involves the shallow insertion of very fine needles into 7 points in your body. Most people describe it as a painless experience. The needles come in a plastic tube, and the tube is placed on the skin while the needle is quickly tapped in. Once the needles are in, every few minutes they will be rotated quickly, without being pushed deeper or pulled out. This again is usually not felt at all. The areas of the body where a needle will be inserted are around your knees, elbows, feet and the top of your head. They will be removed quickly after 20 minutes, this also is usually not felt.

One of the two acupuncture sessions you receive will be a "sham" session, meaning the needles will be placed in points that aren't real acupuncture points. They are completely harmless points, and will be inserted and rotated with the same care and attention as "real" acupuncture.

During the 2 weeks between the tests, you will be asked to record a daily log of your activities, and be instructed to keep your activities between the tests as "normal" as possible (for example, keep doing your regular level of exercise and activity, with no big increases or decreases). Similarly you will be asked to maintain a normal diet, and record a log of your main meals during the day.

Possible Benefits: The possible benefit to you for participating in this study is that you may experience improved performance during the simulated 20km time trial with an intervention of acupuncture. You will also further research into the scientific knowledge of acupuncture.

Possible Risks: Following any physical fitness test to exertion, common side effects may include shortness of breath and light-headedness. Muscular discomfort can range from mild to severe based on your previous level of fitness and sport specificity (this test involves indoor stationary cycling). Cardiovascular complications are rare based on your PAR-Q scores, however if any chest pain or prolonged discomfort are experienced you are required to immediately inform one of the testers, or contact medical emergency personnel if symptoms occur after leaving the test. Delayed-onset muscle soreness on the following day after testing may be present. This is a common sign post intense exercise and should resolve gradually after 48 hrs. If it does not, please call the tester (780-492-5765).

With acupuncture, occasional side effects are mild bruising or discomfort at the needle sites. Minor bleeding at the needles site upon needle removal is a rare occurance. If the site is not cleaned properly prior to needling, infection is also a possibility. Again if any light-headedness is experienced following acupuncture and during testing, immediately inform the tester. This is a very rare complication of acupuncture.

If you have any further questions, please ask. And if you have any questions regarding the possible post-test complications, we will be happy to address them before testing.

Confidentiality: All information will be held confidential, except when professional codes of ethics or legislation requires reporting. The information taken from you, and any data recorded from the testing will be handled solely by Sat Dhillon, the co-investigator. The primary investigator, Dr. David Magee, and the HREB (Health Research Ethics Board), will also have access to this information. The information you provide will be kept for at least five years after the study is done and then destroyed in a confidential manner. The information will be kept in a secure area

(locked filing cabinet). Your name or any other identifying information will not be attached to the information you gave. Your name will also never be used in any presentations or publications of the study results.

Voluntary Participation: You are free to withdraw from this research study at any time. If any knowledge gained from this or any other study becomes available which could influence your decision to continue in the study, you will be promptly informed.

Contact Names and Telephone Numbers:
Please contact any of the individuals identified below if you have any questions or concerns:

Dr. David Magee PhD, PT, Primary Investigator	780-492-5765
Sat Dhillon BScPT, Co-Investigator	780-492-5765

A neutral person to contact about the study is Dr. Paul Hagler, at the Faculty of Rehabilitation Medicine, University of Alberta (780.492.9674).

Appendix M Consent Form

The Acute Effect of Acupuncture on 20km Cycling Performance

Part 1: Researcher Information

Name of Principal Investigator: David Magee, PT, PhD
Affiliation/Contact Information: Dept of Physical Therapy / david.magee@ualberta.ca

Name of Co-Investigator/Supervisor: Sat Dhillon, BScPT
Affiliation/Contact Information: MscPT student / satpal@ualberta.ca

Part 2: Consent of Subject

	Yes	No
Do you understand that you have been asked to be in a research study?		
Have you read and received a copy of the attached information sheet?		
Do you understand the benefits and risks involved in taking part in this research study?		
Have you had an opportunity to ask questions and discuss the study?		
Do you understand that you are free to refuse to participate or withdraw from the study at any time? You do not have to give a reason and it will not affect your care.		
Has the issue of confidentiality been explained to you? Do you understand who will have access to your records/information?		
Do you want the investigator(s) to inform your family doctor that you are participating in this research study? If so, please provide your doctor's name:		

Part 3: Signatures

This study was explained to me by:_____

Date:_____

I agree to take part in this study.
Signature of Research Participant: _____

Printed Name: _____

Witness (if available):_____

Printed Name: _____

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

Researcher:_____

Printed Name:_____

Appendix N
Subject Diet and Activity Log

Please record any changes in your regular eating, sleeping or activity patterns in the following table, including any medication taken. Each cell represents a day, with the days of testing labeled "Test 1, Test 2, and Test 3".

Food- Sleep- Activity-	Food- Sleep- Activity-	Food- Sleep- Activity-	Food- Sleep- Activity-	Food- Sleep- Activity-	Food- Sleep- Activity-	Test 1
Food- Sleep- Activity-	Food- Sleep- Activity-	Food- Sleep- Activity-	Food- Sleep- Activity-	Food- Sleep- Activity-	Food- Sleep- Activity-	Test 2
Food- Sleep- Activity-	Food- Sleep- Activity-	Food- Sleep- Activity-	Food- Sleep- Activity-	Food- Sleep- Activity-	Food- Sleep- Activity-	Test 3